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Nexium gets nod in Japan for gastric ulcer

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Nexium gets approval in Japan for gastric ulcer

Singapore: AstraZeneca has received approval from the Japanese Ministry of Health, Labour and Welfare for a supplemental New Drug Application (sNDA) for the proton pump inhibitor, Nexium Capsule (esomeprazole magnesium) 10mg and 20mg, for the prevention of recurrence of gastric ulcer and duodenal ulcer in patients treated with acetylsalicylic acid (ASA) at low doses.

By preventing the formation of blood clots, low-dose ASA (commonly known as aspirin) has been a mainstay in the prevention of myocardial infarction and ischemic stroke in Japan in recent years against the backdrop of a steadily graying population and the rapidly increasing number of patients with lifestyle related diseases, such as high blood pressure, diabetes and hyperlipidemia. However, the long-term administration of ASA is known to be associated with a risk of peptic ulcers. Because low-dose ASA is used to control the blocking of blood vessels and the formation of blood clots, in most cases

discontinuing administration is not a viable option.

Consequently, there is a need for an appropriate measure for the advance prevention of serious complications in the upper digestive tract. Based on this unmet medical need, Asian Phase 3 clinical trials using NEXIUM Capsules were conducted jointly in Japan, South Korea, and Taiwan on patients who are receiving long-term administration of low-dose ASA

Nexium capsule 20mg once daily demonstrated statistically significantly superior gastric ulcer/duodenal ulcer preventive effect over placebo, and was found to be safe and well tolerated. Based on the positive results of the trials, AstraZeneca submitted an application for the additional indication.